IN THE UNITED STATES DISTRICT COURT
FOR THE
WESTERN DISTRICT OF NORTH CAROLINA
CHARLOTTE DIVISION

UNITED STATES OF AMERICA, and the STATES OF CALIFORNIA, COLORADO, CONNECTICUTT, GEORGIA, HAWAII, ILLINOIS, IOWA, MARYLAND, MASSACHUSETTS, NEW YORK, NORTH CAROLINA, VIRGINIA, AND WASHINGTON, *ex rel.* **WARREN CHRISTOPHER WALL,** **Plaintiffs,**	**Civil Action No. 1:13cv42**
vs.	**SECOND AMENDED FALSE CLAIMS ACT COMPLAINT AND DEMAND FOR JURY TRIAL**
BAXTER INTERNATIONAL, INC., and BAXTER HEALTHCARE CORPORATION, **Defendants.**	***FILED UNDER SEAL*** **PURSUANT TO 31 U.S.C. § 3730(b)(2)**

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GLOSSARY OF TERMS

CFRs	Code of Federal Regulations
cGMPs	Current Good Manufacturing Practices
DOD	Department of Defense
FCA	False Claim Act, 31 U.S.C. § 3729, *et. seq.*
FDA	Food and Drug Administration
FDC Act	Federal Food, Drug and Cosmetics Act, 21 U.S.C. §§ 301 *et. seq.*
HVAC	heating, ventilation and air conditioning
North Cove	Defendant Baxter's IV manufacturing plant in Marion, NC
QA	Quality Assurance
SOPs	Standard Operating Procedures
VA	Veterans Administration
VHA	Veterans Health Administration

PLAINTIFF'S COMPLAINT PURSUANT TO
FEDERAL AND STATE FALSE CLAIMS ACTS

The United States of America and the State plaintiffs set forth below, by and through *qui tam* Relator Warren Christopher Wall, bring this action under 31 U.S.C. §§ 3729 *et seq.*, the Federal and Claims Act, and the State statutes set forth below, to recover from Baxter International, Inc. and Baxter Healthcare Corporation (collectively referred to herein as "Defendant Baxter"), all damages, penalties and other statutory remedies on behalf of the United States, the State plaintiffs and himself and shows the following:

I. INTRODUCTION

1) The claims herein involve the manufacture and sale of adulterated intravenous ("IV") drugs by Defendant Baxter throughout the country. Defendant Baxter, by and through a number of its managers working at a plant in North Carolina, manufactured illegally adulterated drugs by knowingly allowing mold to grow in a "clean room" in direct proximity to where the drugs were filled into IV bags.

2) Mold is known to cause several medical conditions in humans including, but not limited to, severe allergic reactions, mycotoxin toxicity, and various fungal infections including those of the lungs, skin and fungal meningitis - which in some cases may lead to death.

3) Defendant Baxter knowingly failed to remediate the insanitary conditions over a period of no less than 16 months and created false and misleading records which concealed the presence of mold.

4) The adulterated IV drugs were illegal to produce, possess, distribute, sell or dispense, and Defendant Baxter knowingly engaged in a course of conduct designed to conceal the illegal status of its product.

5) Defendant Baxter sold and invoiced the adulterated drugs under sales contracts which stated that the IV drugs conformed to Defendant Baxter's specifications. Defendant Baxter knew that in producing the adulterated IV drugs in "clean rooms" which were contaminated by mold, those drugs did not conform to its own specifications in that Defendant Baxter had violated its process control specifications.

6) Defendant Baxter had a duty to disclose the illegal status of the adulterated IV drugs it was selling during the relevant time, and knowingly failed to make such disclosures, notwithstanding the falsity of the warranties under which they were sold.

7) Defendant Baxter made and caused to be made false claims for payment for these adulterated drugs from the United States through (a) direct sales to the Government, (b) claims for payment to medical providers who were recipients of Government funds and which payments were used to administer and advance the Medicare and Medicaid programs, and (c) subsidies from the Government to the States through the Medicaid program.

8) Defendant Baxter also made and caused to be made false claims for payment for these adulterated drugs from various state governments through their reimbursements to medical providers through the Medicaid programs.

9) Defendant Baxter knew of the mold infestation no later than July 2011 and allowed it to persist until inspectors with the Food and Drug Administration ("FDA") discovered the mold during an inspection in November 2012, which was prompted by a report from Relator Wall. This time period will be hereinafter referred to as "the relevant time."

10) The False Claims Act ("FCA") creates a cause of action against any person or corporation who knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval under 31 U.S.C. § 3729(a)(1)(A) and imposes liability on any person or corporation who

knowingly makes, uses or causes to be made or used, a false or fraudulent record or statement material to a false or fraudulent claim on a recipient of Federal funds under 31 U.S.C. § 3729(a)(1)(B).

11) During the relevant times, 13 states also had false claims acts which made the fraudulent acts by Defendant Baxter actionable in the same manner as the Federal FCA.

12) These state statutes will hereinafter be referred to collectively as the "State FCAs."

13) The Federal and State FCAs allow any person having knowledge of a false or fraudulent claim against the United States, or state governments, to bring an action in Federal District Court for himself and for the United States and state governments and to share in any recovery as authorized by 31 U.S.C. § 3730 and the State FCAs.

14) Wall's claim of entitlement to a portion of any recovery obtained by the United States and the various state governments as *qui tam* Relator is based upon his being the first to file, and in any event his being the original source of the allegations in this Complaint.

15) Should the Court find there has been a public disclosure of the allegations or transactions alleged herein, which Wall specifically denies, Wall is the original source of the information upon which this action is based and brings this action based on direct and independent knowledge of the information on which the allegations are based.

16) As required by 31 U.S.C. § 3730(b)(2), Wall has provided the United States Attorney for the Western District of North Carolina, the attorneys general for the states named as plaintiffs, with statements of the material evidence and information he possesses which supports the claims herein. The disclosure statements contain information which is covered by the attorney-client privilege and/or is attorney work product. It is understood that the United States Attorney's office and the various state attorneys general will treat the disclosure statement as confidential material.

17) The terms "knowing" and "knowingly" are defined in the Federal and State FCAs to include actual knowledge, acting in deliberate ignorance of the truth or falsity of information, and acting in reckless disregard for the truth or falsity of information.

18) The terms "knowing," "knowingly," "know," "known," and "knew," when used hereinafter in this Complaint include having actual knowledge, acting in deliberate ignorance of the truth or falsity of information, and acting in reckless disregard for the truth or falsity of information.

II. JURISDICTION AND VENUE

19) This court has jurisdiction over this civil action pursuant to 28 U.S.C § 1331, 28 U.S.C. § 1367 and 31 U.S.C. §§ 3732 and 3730, and would have supplemental jurisdiction of any State FCA claims under 28 USC 1367 and 31 U.S.C § 3732(b).

20) Personal jurisdiction and venue are proper in this District pursuant to 28 U.S.C. §§ 1391 (b) and (c) and 1395(a) and 31 U.S.C. § 3732(a), as at least one of the defendants is found, has or had an agent or agents, has or had contacts, and transacts or transacted business and their affairs in this judicial district.

21) To Wall's knowledge, jurisdiction over this action is not barred by 31 U.S.C. § 3737(e): there is no civil suit or administrative proceeding involving the allegations and transactions herein to which the United States is a party, there has been no "public disclosure" of these allegations or transactions, and Wall is the "original source" of the information upon which these allegations are based.

III. PARTIES

22) Wall is a citizen of the United States and a resident of Marion, North Carolina. He has been employed by Defendant Baxter in the maintenance department at its plant near Marion (which is called the "North Cove" plant) since 1979, with the exception of 4 years

during which he was in the United States Air Force while on service leave from Baxter. Until his reassignment to another department following the FDA investigation relating to this issue, he was a heating, ventilation and air conditioning ("HVAC") technician at North Cove for 12 years. He obtained knowledge of the facts alleged in this Complaint through his employment with Defendant Baxter.

23) The United States (also referred to herein as the "Federal Government" or the "Government"), pays for medical expenses through various Federal programs and departments including but not limited to Medicare, Medicaid, TRICARE, the Veterans Administration ("VA"), and the Department of Defense ("DOD").

24) The following states pay for medical expenses through the Medicaid program and other medical assistance programs and had enacted State FCAs which made Defendant Baxter's fraudulent acts actionable: California, Colorado, Connecticut, Georgia, Hawaii, Illinois, Iowa, Maryland, Massachusetts, New York, North Carolina, Virginia, and Washington. These states are hereinafter collectively referred to as the "state governments." These state governments have been defrauded by Defendant Baxter's making and causing to be made false claims for payment and making false records regarding the production of adulterated drugs at its North Cove plant.

25) The United States and state governments have been defrauded by Defendant Baxter's making and causing to be made false claims for payment and making false records regarding the production of adulterated drugs at its North Cove plant.

26) Defendant Baxter International, Inc. ("Baxter International") is a Delaware corporation with its principal place of business located at One Baxter Parkway, Deerfield, Il

60015-4633. Defendant Baxter Healthcare Corporation ("Baxter Healthcare"), a wholly owned subsidiary of Baxter International, is a Delaware corporation with its principal place of business located at One Baxter Parkway, Deerfield, Il 60015-4633. Baxter International and Baxter Healthcare (hereinafter collectively referred to as "Defendant Baxter") are diversified healthcare companies that individually, and/or in combination with one another, engage in the business of manufacturing, distributing, marketing, and/or selling IV bags filled with drugs. Baxter Healthcare holds record title, operates and manages the manufacturing facility for IV bags and drug codes in Marion, North Carolina that is known internally at Defendant Baxter as the "North Cove" plant.

IV. IV DRUG PRODUCTION AT NORTH COVE / HEPA FILTRATION ON FILL LINE #11

A. Overview of North Cove Drug Production and Line 11 Drugs

27) Defendant Baxter maintains 67 manufacturing facilities around the world, one of which is the North Cove plant located in Marion, NC. North Cove is the largest manufacturing facility in the world for IV solutions in flexible containers.

28) The North Cove plant is situated on 32 acres, has 2100 employees, has 1.4 million square feet under roof, and produces 1.5 million IV solution units a day, which Defendant Baxter claims is 60% of the IVs sold in the United States.

29) North Cove manufactures plastic IV bags from raw materials, mixes and processes the component ingredients of the drugs being filled into the IV bags, fills the bags, packages them, sterilizes the filled bags, stores, and ultimately ships the finished product throughout the United States.

30) North Cove manufactures IV bags filled with approximately 300 different finished IV drugs. The specific drugs being filled into IV bags are classified and commonly referred to as "codes."

31) The rooms where finished IV bags are filled with the drug codes are called "fill lines."

32) Lines 10 and 11 are the two largest capacity production lines at North Cove. The air filtration system on Line 11 was the location of the mold which is the subject of this Complaint.

33) Three-hundred thousand IV bags are produced on Line 11 every day. This is approximately 12% of all IV drugs sold and administered throughout the United States.

34) Four codes comprise the majority of the drugs filled in Line 11 and these four are among the most frequently administered IV drugs on the market:

- Code 2B1074X – 5% Dextrose with 0.45% Sodium Chloride USP
- Code 2B1064X – 5% Dextrose with 0.9% Sodium Chloride
- Code 2B1324X – 0.9% Sodium Chloride (also called "normal saline")
- Code 2B2324X – Lactated Ringers Injection

35) Clinically, these IV drugs are given to patients in both hospital inpatient and outpatient (urgent care, emergency rooms, and outpatient surgery) settings. The dextrose with sodium chloride codes are used in adults and pediatric patients as sources of electrolytes, calories and water for hydration. Normal saline is used for fluid and electrolyte replenishment

(no nutritional caloric content from dextrose).. Lactated Ringers is very similar to normal saline but has lactate, potassium and calcium added. Both normal saline and Lactated Ringers are used for fluid resuscitation after a blood loss due to trauma, surgery, or a burn injury.

B. Manufacturing Operations on Line 11

36) Line 11 has 3 automated filling machines and one manual station. Pre-mixed drug codes are piped into Fill Line 11 from tanks outside of the rooms. In the automated machines, IV bags are loaded at one end and the drug code is stamped on the bag.

37) The bags are then passed through a section of the machine where nozzles are inserted into the bags and the drug code solution is injected into the bags. This is done at high pressure in order to fill the bags rapidly, and it is not uncommon for missed nozzle insertions to allow the drug solutions to splash up from the machine, sometimes onto the ceiling.

38) After being filled, the IV bags move to the end of the machine where they are sealed and transported out of the room on a conveyor belt. In the next stage of production, the IV bags are subjected to high heat in a step designed to sterilize the contents.

39) All of the fill lines (including Line 11) are rooms which are mandated by FDA regulation to be "clean rooms," designed to minimize particulate and biological matter in order to avoid contamination of the solutions as they are loaded into the IV bags.

40) In order to limit contamination of the solutions as the IV bags are filled, workers in the room wear full cover from head to foot including surgical masks over their faces.

41) Positive pressure is maintained in the room at all times so that outside air, which can carry contaminants, does not flow in when the doors are opened.

42) One of the most important anti-contamination measures in these clean rooms is the HEPA filtration system. HEPA is an acronym which stands for High Efficiency Particulate Air filtration. To qualify as HEPA by Government standards, an air filter must remove 99.97% of all particles greater than 0.3 micrometers from the air that passes through.

43) The sole purpose of this mandated HEPA filtration system is to prevent airborne particles from entering the fill line clean rooms, where such particles present a safety risk of contamination to the drugs as they are filled into the IV bags.

C. HEPA Filters on Line 11

44) Line 11 is a room which is approximately 70x70 feet. The main HVAC plenum is approximately a 50x50 foot square box on the ceiling that is 3 feet deep and is situated directly above the 3 automated fill machines, roughly in the center of the room.

45) The bottom of the plenum is a grid of channels, into which fit 122 HEPA filters (each of which is 2 feet wide by 4 feet long) mounted directly next to one another, and effectively forming a ceiling full of HEPA filters.

46) Air is forced from the plenum down into the room through the filters.

47) On Line 11, a grid of perforated stainless steel protective screens is hung approximately 12 inches below the filters. Looking up at the ceiling from beneath the plenum, only the stainless steel screens are visible. Though the screens block the view of the HEPA filters above, the screens are patent and provide no barrier to the introduction of particulate matter and micro-organisms into the clean room.

48) Line 11 is shut down once a year in July for annual cleaning and maintenance.

49) During that annual shutdown, Wall and other HVAC technicians pull down the stainless steel screens on the ceiling, inspect the HEPA filters, and re-certify every one by testing to make sure that they are in compliance with FDA regulations. This process, like all at North Cove, is dictated by internal standard operating procedures ("SOPs") promulgated by Defendant Baxter pursuant to FDA regulations and current good manufacturing processes ("cGMPs").

V. BAXTER FILLED IV BAGS ON LINE 11 KNOWING THAT THERE WAS MOLD CONTAMINATION IN THE CLEANROOM

A. Mold on the HEPA Filters in July 2011

50) Mold had been observed occasionally at the Baxter North Cove plant since approximately 2001. This included occasions when mold had been found on HEPA filters.

51) When mold was discovered on a HEPA filter prior to July 2011, the filter was replaced by the HVAC technicians pursuant to regulations, cGMPs, and internal SOPs, and without any objections or interference from management.

52) For some time prior to the July 2011 annual inspection of Fill Line 11, mold had been proliferating at a higher than normal rate on the HEPA filters in Line 11 and had been growing on the downstream (room-side) of the HEPA filters themselves, the framework to which they are mounted ("channels"), and on the top-side of the protective screens which cover the filters that are not visible from within the room.

53) Wall first discovered this outbreak of mold on the HEPA filters while performing the annual inspection and FDA certification on Fill Line 11 on or about the first week of July 2011.

54). There were 17-19 HEPA filters with substantial growth of mold on them. By comparison to prior experience, this was an unprecedented percentage of HEPA filters with mold. The highest concentration of contaminated filters and the most substantial growth was on the filters located directly above the area in which the nozzles were inserted and the bags filled.

55) The concentration of mold directly above the area in which IV bags are filled may have been caused by a combination of the splashing solutions as described above, the fact that many of the codes contained sugar (a nutrient), and daily flushing on the fill machine using steam, which rose into the area of the HEPAs and provided warm moisture that would have encouraged microbial growth.

56) Due to its density and location on the down-stream side of the HEPAs, it is foreseeable and likely that material from this mold was being blown directly onto the IV solutions being filled on Fill Line 11 and onto the IV bags as they were being filled.

B. Management Interference in HEPA Replacement in July 2011

57) When they discovered this outbreak, Wall and Darryl Wright, an HVAC technician working with Wall, began to replace all of the HEPA filters that had mold on them.

58) When all but 5 filters had been replaced, Defendant Baxter's Director of Facilities David Allgood came into Line 11. Wall and Wright showed him the mold and explained what they were doing, but Allgood told them to stop and left the room.

59) 3 of the 5 filters were largely covered with black mold and the remaining two had numerous visible block spots.

60) A few minutes after Allgood left Line 11, the Defendant Baxter's Central Maintenance Department Manager, Mike Morley, came in and reiterated that Allgood had ordered them to stop changing filters. Wall and Wright showed Morley the mold on the remaining 5 filters, but Morley insisted that they stop.

61) Shortly after Morley left the room, Defendant Baxter's HVAC Supervisor, Tim Carson entered with the express purpose of confirming that Wall and Wright had followed Allgood and Morley's orders to stop and not replace the 5 filters with mold on them.

62) Wall and Wright complied with those direct orders, did not replace the 5 HEPA filters in question, and closed the screens back up thereby concealing the mold contamination.

63) The presence of mold on and around the HEPA filters directly above the fill machines on Line 11, and the decision to leave it in place violated various Federal regulations, cGMPs, and Baxter internal SOPs, and constituted deviations requiring written reports to be made and maintained with the process control records.

64) As set forth below, the known presence of mold also constituted a breach of a material term in Baxter's sales contract with every one of its customers, which included but were not limited to the United States Government, state governments, and medical providers giving care to Medicare and Medicaid recipients.

C. Defendant Baxter's Managers Knew the Contaminant was Mold

65) Allgood, Morley and Carson knew and intentionally disregarded the fact that the black substance covering and on the HEPA filters was mold, a microbial contaminant.

66) Wall and Wright referred to it as "mold" when they discussed it with Allgood, Morley and Carson in July 2011.

67) On previous occasions where similar black material had been observed, employees and managers referred to the substance as "mold."

68) Upon information and belief, every employee and manager at North Cove had been required to take a training module entitled "Contamination." This training module concentrated on "the two contaminants most affecting [North Cove's] operation," one of which was micro-organisms. It further instructed that the "two groups of microbes that are most important in considering contamination control for our product are bacteria and *mold*." The training materials described colonies of mold and stated that they "loaded the environment with a massive amount of contamination." It also explained that moist conditions encourage its growth. Finally, the Contamination module emphasized that "mold is extremely damaging, generates seeds, shed particles from the material to which they are attached, and by virtue of their presence, advertise neglect."

69) Prior experience and training led to the knowledge among employees that the black growing substance was mold. Defendant Baxter managers Allgood, Morley and Carson knowingly and affirmatively stopped Wall and Wright from remediating, removing and sanitizing a known dangerous contaminant.

70) As set forth below, Defendant Baxter's written SOPs address degraded or damaged HEPA filters and required that they be replaced. In preventing Wall and Wright from replacing the filters in July 2011, Defendant Baxter managers Allgood, Morley and Carson deviated from the SOPs.

71) Notwithstanding the Federal regulations set forth below which require making a written report documenting a deviation and explaining why the decision was made to deviate, upon information and belief, no such report was made or retained.

D. Fall 2011 Knowledge and Inaction by the Plant Manager

72) On October 31, 2011, Wall met with the Plant Manager Mike Howell. Howell was the highest ranking manager of Defendant Baxter in North Carolina. Wall told Howell about the mold on the HEPA filters in Line 11 and described how Allgood, Morley and Carson had prevented Wall and Wright from remediating the contamination in July and caused the mold to remain in the clean room.

73) At Howell's request, Wall and Wright both gave written statements to Human Resources Manager Nan Davis the following day which detailed the same facts.

74) Upon information and belief, if that report was to be used to record a deviation, it would have been directed to a manager on the production side of the plant or a manager in Quality Control, not Human Resources. This report to Human Resources was not a deviation report as was required by FDA regulations and internal Baxter SOPs.

75) In or about December 2011, HVAC Supervisor Tim Carson told Wall that he had re-examined some of the HEPA filters on Line 11and that there were more than the 5 filters with mold on them.

76) Carson told Wall that Defendant Baxter managers intended to replace all the HEPA filters on Line 11 with mold on them during the annual shutdown in July 2012, which was 7 months away.

77) Despite the known mold then-existing on Line 11 and Defendant Baxter's obligations under Federal law, cGMPs, and its own SOPs to immediately eliminate all mold on Line 11, Howell, Allgood, Morley and Carson took no steps to cease production or remediate non-compliant conditions and deviations.

78) As set forth below, several of Defendant Baxter's SOPs addressed degraded or damaged HEPA filters and required that they be replaced. In knowingly allowing the filters with mold to remain on Line 11, the Defendant Baxter's Plant Manager Howell knowingly approved deviations from the SOPs.

79) As set forth below, it was illegal to manufacture, produce, distribute or dispense such drugs.

80) Notwithstanding Federal regulations which require making a written report documenting the deviation and explaining why the decision was made to deviate, upon information and belief, Defendant Baxter's Plant Manager Howell failed to direct that such a report be made and retained, nor did he personally make a report justifying the deviation.

E. Mold on the HEPA Filters in July 2012

81) The 2012 annual maintenance shutdown on Line 11 began on June 30th.

82) Wall and Wright were the only HVAC technicians for the maintenance and certification of the HEPA filters. In the past, other staff were assigned to assist with filter recertification, cleaning, and replacement, if necessary. No explanation was given as to why no additional staff was provided.

83) When Wall and Wright pulled down the stainless steel screens on the ceiling, they discovered that a significantly higher number of HEPA filters had mold growing on them.

84) 29 HEPA filters exhibited moderate to severe mold infestation. Approximately 25 of the stainless steel screens exhibited mold growing on the top-side. Also present this time was substantial mold growing on the mounting channels surrounding approximately 15 of the affected screens. In certain places, mold was growing invasively in the gel medium which formed a seal between the HEPAs and mounting channels.

85) Exhibit #1 is a photograph taken by Wall during the July 2012 shutdown depicting a section of the ceiling on Line 11 with the stainless steel screens hanging down during annual maintenance. A plastic shrouded top of one of the fill machines appears at the lower left corner of the photograph. Clean HEPA filters are visible diagonally through the center of the photograph, mounted in the white painted channels.

86) Exhibit #2 is a photograph taken by Wall during the July 2012 shutdown depicting a filter showing visible mold on approximately 50% of the surface area. Mold is also visible on all the channels as well.

87) Exhibit #3 is a photograph taken by Wall during the July 2012 shutdown depicting a filter showing visible mold on approximately 100% of the surface area.

88) Exhibit #4 is a photograph taken by Wall during the July 2012 shutdown depicting a channel at the intersection of 4 HEPA filters with black mold growing in spots over a significant portion of the surface area.

89) Exhibit #5 is a photograph taken by Wall during the July 2012 shutdown depicting the top-side surface of one of the stainless steel screens with raised spots of mold growing over a significant portion of the surface area.

90) On or about June 30th, Wall and Wright showed the Line 11 mold infestation to Defendant Baxter's Chief Plant Engineer Stan Cooke, Cooke climbed the ladder and examined the mold at close range.

91) After discussing the mold with Wall and Wright, Cooke left the Line 11 room and encountered Allgood and Morley directly outside the door. Within minutes, Cooke radioed Wall and told him that Allgood had ordered that Wall and Wright "just wipe it off."

92) HEPA filters are fragile and cannot be wiped off. According to Defendant Baxter policy, even if such contamination was found on a cleanable surface it could not be "wiped off," but rather had to be thoroughly cleaned and sanitized with chemical disinfectants.

93) On July 1, 2012, Carson told Wall and Wright that 'Whatever you do, do not bring up changing the HEPA filters.'

94) Wall and Wright did not replace the HEPA filters, but the screens were left open and left the filters exposed. On or about July 2nd, Defendant Baxter's Plant Manager Howell was in Line 11. While observing the ceiling and HEPA filters, and with knowledge that there was substantial mold growing, Howell directed Facilities Engineer Steve Pittman to "get the screens put back up … and have them cleaned." Thus, the highest ranking Baxter manager in North Carolina had again knowingly ordered that the deviation condition remain in place for what he knew would be another year until the July 2013 shutdown.

F. The False HEPA Certification Report

95) On July 3, 2012, Wall filled out a HEPA certification report and wrote on the form: "what appears to be mold on numerous filters."

96) In or about mid-July, David Allgood met with Wall to discuss his HEPA certification form. Allgood informed Wall that he did not want Wall to make such notes on the certification reports, suggesting that they had talked about "open-ended comments" previously. Allgood had not spoken to Wall about notations like these before.

97) The following day, Wall was directed by Carson to write a statement about the July 2102 shutdown and his observations and actions regarding the mold. Wall was told again to give the statement to Human Resources Manager Nan Davis, rather than a manager in production or Quality Control.

98) Wall wrote his statement on July 18, 2012. In it he described the mold observed on Line 11 earlier in the month and set forth the actions of Cooke, Allgood and Morley in preventing the filter replacement. Wall does not know what Defendant Baxter did with that statement.

99) Upon information and belief, in or about late-July 2012, Plant Engineer Stan Cooke marked 8 selected filters on a HEPA "filter map" of Line 11 (a schematic diagram of the 122 filters) and gave it to HVAC supervisor Carson and HVAC techs Fred Procter and Rouse Roberts. Cooke directed them to go into Line 11 and inspect only those filters.

100) Cooke knew the location of the HEPA filters with mold because he had been shown them all by Wall and Wright on June 30th. Upon information and belief, Cooke had selected 8 clean HEPA locations with the intent to avoid the detection of the known mold

elsewhere, and for the purpose of generating a report which would falsely note the absence of mold.

101) Upon information and belief, no mold was found on the filters selected by Cooke by Carson, Procter and Roberts during that re-inspection.

102) Thereafter on July 30th, Carson wrote a note on the July 3rd HEPA inspection report. It stated "7/29 follow-up inspection was performed on HEPA filters on Line 11. NO discoloration was found on the HEPA filters. No HEPA filters were in need of replacement." Central maintenance Manager Mike Morley signed the report on August 1st.

103) Cooke, Carson, and Morley knew that there were many HEPA filters on Line 11 that had active mold growth on them and the adjoining surfaces. This August 1st HEPA certification report was false because Cooke, Carson, and Morley knowingly and intentionally concealed the mold which constituted a reportable deviation.

104) Upon information and belief, the "filter map" marked with the 8 filters chosen to be re-inspected is missing and cannot be located on the North Cove premises.

G. Failure to Adequately Perform Environmental Monitoring on Line 11

105) As set forth below, Defendant Baxter was required to establish an environmental monitoring program in all clean rooms. Part of that program was to conduct regular air sampling and surface "swipe testing" for particulate and microbial contamination.

106) Upon information and belief, the protocol for air testing on Line 11 did not abide by the SOPs. Specifically:

(a) Based upon the cubic footage of the Line 11 clean room, a minimum of 9 sample locations had to be established, but only 7 locations were specified. This under-sampling was known by Defendant Baxter's management since before the relevant time, but it was not corrected.

(b) The sampling locations were required to be chosen based upon, among other things, location of production. Notwithstanding this requirement, neither air nor surface testing was regularly performed in the part of the room among the fill machines or under the HVAC plenum and HEPA filters.

VI. IV BAGS FILLED ON LINE 11 CONTAINED "ADULTERATED DRUGS" AS DEFINED BY LAW

A. Overview of the Regulatory Scheme

107) The Federal Government endeavors to ensure the safety and efficacy of drug products consumed daily by millions of Americans through a combination of an FDA new drug approval process, self-regulation by manufacturers of the manufacturing process, and intermittent FDA inspections.

108) As the FDA's Deputy Associate General Counsel, Eric M. Blumberg, Esq., wrote, drug manufacturers "occupy a virtual fiduciary relationship to the public … FDA shares this trustee relationship to the consumer with industry leaders, but the initial and ultimate responsibility remains with those leaders. This is true not only because the law makes it so, but also for the practical reason that the FDA cannot be in every factory, much less monitor every decision that is made every day that affects the quality of our foods and drugs." Abbott

Laboratories Consent Decree and Individual Responsibility Under the Federal Food, Drug and Cosmetic Act, 55 Food and Drug L.J., 145, 147.

109) Thus, the Federal Government relies on drug manufacturers to self-regulate in a system where drugs and manufacturing processes are approved at inception. Thereafter, drug manufacturers are required to promulgate written standards and procedures for manufacturing, follow those written standards and procedures, document the production process, document any deviations from the written procedures and process controls, document any known issues with the drugs it produces, and keep those records available for FDA random inspections and investigations.

110) The retention of those records and their accuracy are a critical component to insuring the safety and efficacy of all drugs administered in the United States.

B. Line 11 Drugs were "Adulterated" by Statutory Definition

111) Pursuant to federal law, (21 U.S.C. § 351(a)(2)(A)), a drug is adulterated "if it has been prepared, held, or packed under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health."

112) From no later than July 2011 and continuing to November 2012, Defendant Baxter, by and through its managers, Howell, Allgood, Cooke and Carson, knew and had reason to believe that the Line 11 clean room was contaminated with microbial organisms, to wit, mold, which they knew could be injurious to the health of patients to whom they were administered.

113) Those Baxter managers prevented Wall and others from removing the contaminated HEPA filters and cleaning and sanitizing the associated contaminated surfaces and media.

114) The known presence of mold was an insanitary condition amounting to "filth," as that term is statutorily used, and caused the drugs contained in the IV bags filled on Line 11 during the relevant time to be legally adulterated.

115) Mold is known to cause several medical conditions in humans including, but not limited to, severe allergic reactions, mycotoxin toxicity, and various fungal infections including those of the lungs, skin and fungal meningitis - which in some cases may lead to death.

116) The known presence of mold directly above the fill machines on Line 11 caused a condition whereby the IV bags filled on Line 11 could have been contaminated and rendered injurious to health. As such, all IV bags filled on Line 11 during the relevant time period were legally adulterated.

C. Line 11 Drugs Were Adulterated Because Baxter Violated Numerous "Current Good Manufacturing Practices"

117) Pursuant to federal law, (21 U.S.C. § 351(a)(2)(B) and 21 C.F.R. § 210.1(b)), a drug is adulterated if "the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice …."

118) The FDA has promulgated minimum cGMPs for the methods used in, and the controls to be used for the manufacture, processing, packing and holding of all drugs to assure that they meet the requirements of the Food Drug and Cosmetic Act as to safety and quality.

Pursuant to 21 C.F.R. § 210.1, those cGMPs are found in Parts 211, 225 and 226 of Chapter 21 of the Code of Federal Regulations.

119) These regulations constituted binding, minimum cGMPs for Defendant Baxter's manufacture of the drugs and IV bags processed in the clean room on Line 11.

120) Throughout the relevant time, all of the enumerated IV solutions filled on Line 11 were knowingly and intentionally processed by Defendant Baxter using controls which did not conform to and were not operated in conformity with various applicable cGMPs and were, therefore, adulterated.

121) From no later than July 2011, Defendant Baxter, by and through its managers Howell, Allgood, Cooke and Carson knew and had reason to believe that the Line 11 clean room was contaminated with microbial organisms, to wit, mold.

122) Those Baxter managers prevented Wall and others from removing the contaminated HEPA filters and cleaning and sanitizing the associated contaminated surfaces and media.

123) In so doing, Defendant Baxter, by and through its managers Howell, Allgood, Cooke and Carson, knowingly and intentionally violated the following FDA minimum cGMPs:

(a) Pursuant to 21 C.F.R. § 211.42, Defendant Baxter was required to perform operations and maintain control systems "to prevent contamination … during the course of … manufacturing operations." The presence of visible mold growing on the HEPA filters and adjacent surfaces in the ceiling directly above the fill

stations on Line 11 constituted a substantial risk of contamination to the drugs being processed in that clean room.

(b) Pursuant to 21 C.F.R. § 211.46, Defendant Baxter was required to provide safe ventilation and utilize an air filtration system "for adequate control over … micro-organisms." The presence of visible mold growing directly on the downstream side the HEPA filters while air was forced through them into Line 11 constituted the use of an air filtration system which utterly lacked control over micro-organisms and thereby foreseeably, knowingly and recklessly risked contamination of the IV bags and drugs being processed in that clean room.

(c) Pursuant to 21 C.F.R. § 211.56, Defendant Baxter was required to maintain all buildings "used in the manufacture, processing, packing, or holding of a drug products … in a clean and sanitary condition." The presence of a substantial amount of visible mold growing in the clean room on Line 11 was a patently unsanitary condition.

(d) Pursuant to 21 C.F.R. § 211.58, Defendant Baxter was required to maintain all buildings "used in the manufacture, processing, packing, or holding of a drug product … in a good state of repair." The presence of visible mold growing on the HEPA filters and adjacent surfaces in the ceiling of Line 11 was not a good state of repair.

(e) Pursuant to 21 C.F.R. § 211.67, Defendant Baxter was required to clean and maintain all equipment, and sanitize or sterilize it at appropriate intervals to prevent contamination that would alter the safety or quality of the drug products.

Upon being notified of and shown the mold in Line 11, Defendant Baxter, by and through managers, Howell, Allgood, Cooke and Carson, was required to replace all HEPA filters with visible mold on them and clean and sanitize the adjacent affected surfaces, but affirmatively prevented Wall and others from performing these tasks.

D. Line 11 Drugs were Adulterated Because Baxter Failed to Follow Its Own Internal Standard Operating Procedures

124) The regulatory cGMPs also required that Defendant Baxter establish appropriate written procedures designed to prevent objectionable micro-organisms in drug products purporting to be sterile, *and follow them*. 21 C.F.R. § 211.113 (contained in Subpart F: "Production and Process Controls").

125) Thus, in FDA's self-regulatory scheme, Defendant Baxter was required to promulgate and abide by detailed written procedures which comported with the applicable cGMPs and would prevent contamination by micro-organisms, including mold.

126) Because failure to follow those procedures constituted violation of cGMPs, the internal procedures were themselves cGMPs and Defendant Baxter was legally bound to abide by them.

127) Pursuant to 21 C.F.R. § 211.113, Defendant Baxter promulgated those written procedures as internal "Standard Operating Procedures," or "SOPs." Those SOPs set forth production and process controls that would have prevented or remediated the mold growing on Line 11.

128) Defendant Baxter, by and through the actions of managers, Howell, Allgood, Cooke and Carson, affirmatively prevented Wall and others from implementing the following SOPs and remediating the mold:

(a) Baxter SOP Document # 20-06-07-011, entitled "Certification and Monitoring – LVP/SVP Manufacturing and Sterility Test Complexes," set forth HEPA filter conditions which would have justified filter replacement. Filters which were leaking, torn, *or damaged* were authorized to be replaced pursuant to Section 7.2(D) (emphasis added). Prior to the annual shutdown in July 2011, a HEPA filter which showed visible damage from mold growing on it was routinely replaced by the HVAC technician performing the HEPA recertification. In July 2011 and July 2012, Defendant Baxter managers affirmatively prevented Wall from performing this function in compliance with this SOP.

(b) Baxter SOP Document # 11-21-04-006, entitled "Aerosol Challenge of HEPA and ULPA Filters," set forth in Section 3.3.3 a number of factors which indicated that a filter needs to be replaced. Among them was"[w]hen water or chemical damage has affected enough of the surface to weaken or degrade the filter material, *resulting in visible damage"* (emphasis added). Most or all of the filters which Wall and others were ordered by Defendant Baxter managers to leave in place over the HVAC employees' objection in July of 2011 and 2012, had visible mold over a significant portion of the surface and would have been replaced pursuant to this and other SOPs in earlier years.

(c) Baxter SOP Document # CQP0402007, entitled "HVAC Qualification, Monitoring and Maintenance in Cleanrooms, Controlled Environments, and

Separative Enclosures," also set forth (in Section 9.2.2) that a reason for filter replacement was "weakened or degraded filter material resulting in visible damage.' This SOP also listed "[c]leaning of [HVAC] internal surfaces as necessary" among the required maintenance tasks. The mold on the HEPA filters on Line 11 was invasive and constituted a degradation of the material that required replacement. The mold present on the plenum surfaces and framing supporting the HEPAs required cleaning and sanitizing pursuant to this SOP as well. Defendant Baxter managers affirmatively prevented both of these tasks from being performed in violation of this SOP.

(d) Baxter SOP Document # CQP0302008, entitled Design Criteria for Cleanrooms and Associated Controlled Environments," set forth in Table 3 a requirement that the air filtration systems shall be selected (and presumably maintained) "to suit both the cleanliness level required and the conditions associated with their use in the system." Furthermore, Table 3 requires that ceilings be "sealed to prevent ingress of airborne particles and other contaminants." The existence of growing mold on the room-side of the HEPA filters and adjacent surfaces in Line 11 constituted an air filtration system which was, itself introducing contaminants directly into the cleanroom. To the extent that the proximity of splashing sugar-containing codes and daily exposure to steam may have created an environment conducive to the growth of mold, the design was violative of this SOP as well.

(e) Annex 1: Defendant Baxter was also bound to comply with the guidelines set forth in Annex 1, "Manufacture of Sterile Medicinal Products," because it was

incorporated by reference in Baxter's "HVAC Qualification, Monitoring and Maintenance in Cleanrooms, Controlled Environments, and Separative Enclosures" SOP. The Annex 1 sets forth several requirements which Defendant Baxter violated by intentionally allowing the mold to remain on Line 11:

(i) Paragraph 1: "Clean areas should be maintained to an appropriate cleanliness standard and supplied with air which has passed through filters of an appropriate efficiency."

(ii) Paragraph 46: "In clean areas, all exposed surfaces should be smooth, impervious and unbroken in order to minimize the shedding or accumulation of particles or micro-organisms …"

(iii) Paragraph 60: "All equipment such as sterilisers [sic], air handling and filtration systems, air vent and gas filters … should be subject to validation and planned maintenance; their return to service should be approved."

(iv) Paragraph 64: "Precautions to minimize contamination should be taken during all processing stages including the stages before sterilization."

The Annex 1 begins with the grounding principle that Defendant Baxter, by and through its managers, knowingly ignored when they intentionally allowed mold to grow on Line 11. Paragraph #1 states that:

> The manufacture of sterile products is subject to special requirements in order to minimize risks of microbiological contamination, and of particulate and pyrogen contamination. Much depends on the skill, training and attitudes of the personnel involved. Quality Assurance is particularly important, and this type of manufacture must strictly follow carefully established and validated methods of preparation and procedure.

Sole reliance for sterility or other quality aspects must not be placed on any terminal process or finished product test. (emphasis added)

(f) 21 C.F.R. § 211.160 required written specifications for laboratory and environmental testing including sampling plans. SOP # CQP0402004 sets forth the environmental monitoring specifications applicable to the North Cove plant. In Section 6.2, the SOP required that the locations and frequency of environmental monitoring, which were air sampling for particulates and surface swipe testing for microbial contamination, be determined by a risk assessment based on:

- Locations likely to have a high potential for microbial contamination
- Production activities
- Locations likely to be difficult to clean and sanitize
- Historical data, if available
- Performance qualification data
- Line and process configuration
- personnel, product, and/or material traffic patterns

In not establishing air or surface monitoring locations in and around the fill machines or under the air supply, Defendant Baxter ignored all but one of these criteria and violated this SOP: The fill line area was a natural breeding ground for microbes (splashing nutrients coupled with warm moisture), it was the hub of production activities, the machinery and tight spaces made it difficult to sanitize, the discovery of mold in July 2011 on the HEPA filters directly above the line was a red flag that should have triggered testing on the fill machine area, ignoring this critical part of the room removed the line and process from the sampling, and virtually all of the personnel and product traffic was concentrated in the fill line area during production. Failure to test under the air supply would

foreseeably and predictably under sample or miss particulates and microbial contamination being blown from or through the HEPA filters. Upon information and belief, Defendant Baxter also knowingly violated internal SOPs when it under-sampled Line 11 by conducting air sampling at 7, rather than the required 9 locations.

VII. BAXTER MADE FALSE RECORDS WHICH CONCEALED THE FACT THAT THE DRUGS WERE ADULTERATED

129) Because the FDA cannot monitor and police all drug manufacturing activities, the regulatory scheme requires manufacturers to "self-regulate" by following cGMPs (including the company internal SOPs) and record and justify all deviations from those standards. Those records must be kept and made available to FDA inspectors upon request.

130) Throughout the relevant time, Defendant Baxter, knowing of the presence of mold on Line 11, failed to properly investigate, remediate, record or justify those deviations as it was required to do.

131) The records associated with production on Line 11 during the relevant time either knowingly omitted references to mold, or actively mislead and concealed as to the substantial on-going presence of the mold.

132) 21 C.F.R. § 211(a) required written procedures for production and process control. The written procedures applicable to production and process control at North Cove were the Baxter SOPs.

133) 21 C.F.R. § 211(b) required that the SOPs be followed and documented throughout production. It also required that "[a]ny deviation from the written procedures shall be recorded and justified."

134) Beginning no later than July 2011 and throughout the relevant time, Defendant Baxter, by and through Plant Manager Mike Howell, Director of Facilities David Allgood, Central Maintenance Manager Mike Morley, Plant Engineer Stan Cooke, and HVAC Supervisor Tim Carson, knowingly deviated from written SOPs 20-06-07-011, 11-21-04-006, CQP0402007, CQP0302008, and the Annex 1; by preventing Wall and others from replacing the HEPA filters with mold on them and sanitizing the adjacent areas in the Line 11 clean room.

135) Due to the affirmative actions of Defendant Baxter's Plant Manager Mike Howell, Director of Facilities David Allgood, Central Maintenance Manager Mike Morley, Plant Engineer Stan Cooke, and HVAC Supervisor Tim Carson, mold persisted and proliferated in the Line 11 clean room throughout the relevant time.

136) Upon information and belief, records of these deviations were omitted from the process control records in violation of 21 CFR § 211(b) and were inaccessible to the FDA. As such, the process control records for production on Line 11 throughout the relevant time were false.

137) Upon information and belief, Defendant Baxter also omitted records justifying the deviation, as was required by 21 C.F.R. § 211(b).

138) On or about July 2012, Defendant Baxter, by and through Central Maintenance Manager Mike Morley, Plant Engineer Stan Cooke, and HVAC Supervisor Tim Carson, made a

false and misleading process control records – the HEPA re-inspection map and the July 3, 2012 HEPA Inspection Report as edited on July 29th.

139) In directing re-inspection of filters which he knew to be unaffected by mold, and causing the 2012 HEPA certification report to note the absence of mold, Cooke caused that report to be false and misleading.

140) Carson and Morley had personal knowledge that the HEPA filters with mold on Line 11 had been left in place after the annual maintenance was completed earlier that month.

141) Carson and Morley knowingly caused the 2012 HEPA certification report to be false and misleading.

142) Beginning on or before July 2011 and through the relevant time, Defendant Baxter also knowingly deviated from written SOP CQP0402004, by ignoring the specified risk factors and failing to conduct environmental monitoring in and directly around the fill machine area in the Line 11 clean room.

143) Upon information and belief, the laboratory records throughout the relevant time omitted references to or justification for this deviation, as was required by 21 C.F.R. § 211.160. As such, the laboratory records were false.

144) Throughout the relevant time, Defendant Baxter knowingly deviated from written SOP CQP0402004 and other SOPs by taking air samples at fewer than the specified number of locations in the Line 11 clean room.

145) Upon information and belief, the laboratory records throughout the relevant time omitted references to this deviation, as was required by 21 C.F.R. § 211.160. As such, the laboratory records were false.

VIII. BAXTER SOLD ADULTERATED DRUGS IN VIOLATION OF ITS EXPRESS WARRANY

146) Throughout the relevant time, Defendant Baxter sold the adulterated IV drugs through its Medical Products Division. The Government (through DOD and the VHA) and other healthcare providers placed orders for those drugs electronically through Baxter's eServices Center online portal, or using Electronic Data Interchange ("EDI") or Global Healthcare Exchange ("GHX").

147) All sales of the adulterated IV drugs were made pursuant to Baxter's "Terms and Conditions of Sale" (hereinafter "the Agreement"). The Agreement stated that "[a]ll sales are subject to and expressly conditioned upon the terms and conditions contained herein, which are accepted by the customer upon placing an order for product(s) with Baxter which order is confirmed by Baxter."

148) The Agreement incorporated by reference all warranties contained in the label and inserts accompanying the products. Upon belief, those inserts warrantied that the IV drugs conformed to all Baxter specifications.

149) The Agreement also stated that, "in the absence of a more specific warranty, with respect to Products manufactured by Baxter, such Products are warranted to conform to Baxter's specifications for the Product in effect at the time of shipment."

150) Defendant Baxter's compliance with the warranties incorporated in the Agreement was material to, and was a condition precedent to, payment by any and all purchasers.

151) The adulterated IV drugs sold by Defendant Baxter during the relevant time were manufactured in violation of Baxter's process control specifications.

152) As to the sale of those adulterated IV drugs, the warranties were false statements.

153) As to the adulterated IV drugs and throughout the relevant time, the labels and inserts accompanying the drugs, and the Agreement under which they were sold, constituted false statements and were material to false claims for payment.

154) Throughout the relevant time, Baxter invoices made pursuant to the Agreement and other warranties, which were submitted to the Government, medical providers, and state governments for the adulterated IV drugs, constituted false certifications of a material condition to payment, to wit, that the drugs were not adulterated.

155) Throughout the relevant time, Baxter invoices made pursuant to the Agreement and other warranties, which were submitted to the Government, medical providers, and state governments for the adulterated IV drugs, and which invoices failed to disclose that the product violated those warranties and was illegal to sell, constituted fraud by omission as to a material condition to payment.

IX. FACT THAT DRUGS WERE ADULTERATED WAS MATERIAL TO PAYMENT

156) The United States, the medical providers who were recipients of Government funds through Government healthcare programs, and the state governments would not have paid

for, reimbursed, or otherwise subsidized payment for the drugs produced during the relevant time on Line 11 if it knew that they were adulterated.

157) The United States, the medical providers who were recipients of Government funds through Government healthcare programs, and the state governments would not have paid for, reimbursed, or otherwise subsidized payment for the drugs produced on Line 11 if they knew that Defendant Baxter's express warranty contained in the sales contract was a false statement.

158) The United States, the medical providers who were recipients of Government funds through Government healthcare programs, and the state governments would not have paid for, reimbursed, or otherwise subsidized payment for the drugs produced on Line 11 if they knew that Defendant Baxter, by and through its managers, had intentionally created false records as set forth above in order to conceal the fact that all of those drugs were adulterated.

159) The intentional acts of Defendant Baxter's managers, as well as the false records and omissions set forth above, actively concealed the fact that its drugs were adulterated and thus caused the United States, medical providers, and state governments to pay false claims.

160) Pursuant to 21 U.S.C. § 331(a) (c), and (g), it was illegal for Defendant Baxter to manufacture, deliver, or sell the adulterated IV drugs. If the United States, medical providers, and state governments had known the drugs were adulterated, their payment for, reimbursement or subsidy of those drugs would have constituted aiding and abetting an illegal act.

161) Because Defendant Baxter knowingly concealed the contamination and created false and fraudulent process control records to conceal its violation of 21 U.S.C. §331, its distribution of the adulterated drugs constituted a felony pursuant to 21 U.S.C. § 333(a)(2).

162) Pursuant to 18 U.S.C. § 4 and other authorities, Defendant Baxter had a legal duty to disclose the felonious manufacture, distribution and sale of the adulterated IV drugs.

163) Throughout the relevant time and in all instances where the Federal Government purchased the adulterated IV drugs directly from Baxter through the VHA and DOD, the United States itself was receiving and subsequently delivering adulterated drugs and would not have done so or paid Defendant Baxter's claims if they had known the drugs were adulterated.

164) Throughout the relevant time and in all instances in which medical providers purchased the adulterated IV drugs from Baxter in support of Government healthcare programs such as Medicare, Medicaid and TRICARE, those medical providers were receiving and subsequently delivering adulterated drugs pursuant to Defendant Baxter's false statements and false records, and would not have done so or paid Defendant Baxter's claims if they had known the drugs were adulterated.

165) It would have been illegal for the Federal Government, through the VHA or DOD to receive and deliver the adulterated IV drugs if it had known the facts that Defendant Baxter actively concealed and omitted in its records.

166) Furthermore, Defendant Baxter knew that such adulterated drugs were not fit for therapeutic use and that no provider or insurer, including the United States and the state governments, would purchase or pay for the drugs if they knew of the conditions under which they were manufactured.

X. FALSE CLAIMS AND USE OF FALSE RECORDS BY BAXTER

A. Overview of Federal and State Government Payment for the Adulterated IV Drugs

167) Throughout the relevant time, Defendant Baxter knowingly marketed and sold the adulterated IV drugs produced on Line 11 directly to the Federal and state governments, and to healthcare providers who were recipients of Government funds used to advance Government healthcare programs.

168) Defendant Baxter maintained direct sales contracts with the United States and various state governments for sale of its products through its Corporate Government Sales division in Round Lake, Illinois.

169) In 2011, Defendant Baxter published a report acknowledging that it caused claims to be made to the United States.

170) Defendant Baxter specifically stated that it "supplies products and services to healthcare providers that are reimbursed by federally funded programs such as Medicare" and that "the company's activities are also subject to regulation by the Center for Medicare/Medicaid Services and enforcement by the Department of Health and Human Services."

171) In its 2010 SEC Form 10K filing, Defendant Baxter acknowledged causing claims to be made for its products and stated that "[s]ales of Baxter products are dependent, in part, on the availability of reimbursement by government agencies and healthcare programs, as well as insurance companies and other private payers."

172) During the relevant time, the United States paid directly or reimbursed other providers for approximately 24% of all medical care nationwide through Medicare, the Department of Defense ("DOD"), the Veterans Health Administration ("VHA") and other Federal health insurance programs. Additionally, the United States paid approximately 8.5% of

all medical care nationwide as subsidies to the state governments through the Medicaid program. Thus, the United States paid for no less than approximately 32% of all medical bills in the United States.

173) The United States paid a higher percentage of all medical care nationwide when analyzing only hospital care. During the relevant time, the United States paid an aggregate percentage (including Medicare Part A, Part B, DOD, VHA, and Medicaid subsidies) of approximately 45% of hospital care.

174) Upon information and belief, the adulterated IV drugs that were produced on Line 11 were disproportionally used during hospital care, as compared to outpatient care.

175) Upon information and belief and during the relevant time, the Federal Government paid for between 32-45% of all IV drugs administered in the United States.

176) North Cove produced 60% of the IV drugs sold nationwide, with Line 11 being 20% of the overall North Cove production. Thus, approximately 12% of all IV drugs sold throughout the United States were adulterated drugs produced on Line 11 during the relevant time.

177) During the relevant time and upon information and belief, the United States paid for no less than 28 million adulterated IV bags per year which were produced by Defendant Baxter on Line 11.

178) The United States Government paid for the adulterated IV drugs in three ways:

(a) direct payment for purchases by Federal healthcare providers such as the Veterans Health Administration ("VHA"), the Department of Defense ("DOD"), and other direct healthcare providers within the Federal Government;

(b) reimbursements by the Department of Health and Human Services ("DHHS") to various types of healthcare providers (doctors, hospitals, clinics, etc.) through Medicare, which is administered by the Centers for Medicare and Medicaid Services ("CMS"), and reimbursement from DOD whose Military Health System administers the TRICARE military health insurance program; and

(c) Federal subsidies to the states for their Medicaid programs.

179) The state governments pay for healthcare products such as IV drugs in two ways:

(a) reimbursements by the states to healthcare providers (doctors, hospitals, clinics, etc.) through the state Medicaid programs;

(b) reimbursements by many, but not all states to healthcare providers through certain non-Medicaid programs.

B. Direct False Claims on the Government by Baxter

180) The Department of Veterans Affairs ("VA"), through the VHA, operates an integrated healthcare system from over 1800 sites nationwide, including 152 hospitals. It provides medical assistance to people who have been discharged from active military duty. With regard to the use in VHA facilities of the adulterated IV drugs produced on Line 11, the United States directly purchased, received and delivered the drugs to patients.

181). The DOD operates over 30 Military Treatment Facilities ("MTFs") nationwide. These are hospitals and clinics from which it provides medical care for active duty members of the military, their families and some retirees. With regard to the use in MTF facilities of the adulterated IV drugs produced on Line 11, the United States directly purchased, received and delivered the drugs to patients.

182) On September 11, 2012, Defendant Baxter entered into contract #00338008504 with the VHA for the sale of Code 2B1074X IV bags (1000ml 5% dextrose with .45% sodium chloride).

183) All sales under contract #00338008504 were made pursuant the express warranty that the product met Defendant Baxter's specifications as set forth above.

184) Upon information and belief, a majority of the Code 2B1074X IV bags sold to VHA providers pursuant to contract #00338008504, and for which Defendant Baxter submitted claims for payment and was paid by the United States, were adulterated products produced on Line 11.

185) On September 11, 2012, Defendant Baxter entered into contract #00338008904 with the VHA for the sale of Code 2B1064X IV bags (1000ml 5% dextrose with .9% sodium chloride).

186) All sales under contract #00338008904 were made pursuant the express warranty that the product met Defendant Baxter's specifications as set forth above.

187) Upon information and belief, a majority of the Code 2B1064X IV bags sold to VHA providers pursuant to contract #00338008904, and for which Defendant Baxter submitted

claims for payment and was paid by the United States, were adulterated products produced on Line 11.

188) On September 11, 2012, Defendant Baxter entered into contract #00338004904 with the VHA for the sale of Code 2B1324X IV bags (1000ml normal saline).

189) All sales under contract #00338004904 were made pursuant the express warranty that the product met Defendant Baxter's specifications as set forth above.

190) Upon information and belief, a majority of the Code 2B1324X IV bags sold to VHA providers pursuant to contract #00338004904, and for which Defendant Baxter submitted claims for payment and was paid by the United States, were adulterated products produced on Line 11.

191) On September 11, 2012, Defendant Baxter entered into contract #00338011704 with the VHA for the sale of Code 2B2324X IV bags (1000ml Lactated Ringer's).

192) All sales under contract #00338011704 were made pursuant the express warranty that the product met Defendant Baxter's specifications as set forth above.

193) Upon information and belief, a majority of the Code 2B2324X IV bags sold to VHA providers pursuant to contract #00338011704, and for which Defendant Baxter submitted claims for payment and was paid by the United States, were adulterated products produced on Line 11.

194) The 4 VHA contracts set forth above are only examples, and throughout the relevant time, Defendant Baxter knowingly entered into sales of and submitted claims for payment for the adulterated IV drugs to the VHA and DOD.

195) Throughout the relevant time and in violation of 31 U.S.C. § 3729(a)(1)(A), Defendant Baxter knowingly presented false claims for payment to agents or employees of the VHA and DOD, in as much as the invoices submitted pursuant to the sales Agreement constituted false certifications of a material condition to payment, to wit, that the drugs conformed to Baxter's specifications and were not adulterated.

196) Throughout the relevant time and in violation of 31 U.S.C. § 3729(a)(1)(B), Defendant Baxter knowingly made and used false statements to agents or employees of the VHA and DOD, to wit, the false warranty contained in the sales contract stating that the adulterated IV drugs conformed to Defendant Baxter's specifications, and false product inserts, and those false statements had the natural tendency to influence payment of the false and fraudulent claims.

197) Throughout the relevant time and in violation of 31 U.S.C. § 3729(a)(1)(B), Defendant Baxter knowingly made and used false process control records, including but not limited to the "2012 HEPA certification report," which concealed the fact that the IV drugs produced on Line 11 were adulterated, and those false records had the natural tendency to influence payment of the false and fraudulent claims by the VHA and DOD.

198) Throughout the relevant time and in violation of 31 U.S.C. § 3729(a)(1)(A & B), Defendant Baxter made false claims for payment and made and used false statements, to wit, entering into the sale of the adulterated IV drugs to the VHA and DOD when Defendant Baxter had a legal duty to disclose the fact that they were adulterated and did not do so, and that omission had the natural tendency to influence payment of the false and fraudulent claims.

C. False Claims by Baxter Made on Recipients of Government Funds Through the Medicare and TRICARE Programs

199) The adulterated IV drugs produced on Line 11 were administered to patients needing parenteral nutrition, hydration and electrolyte support. Virtually all of these drugs were used during surgical procedures, hospital admissions and in emergency room care.

200) Throughout the relevant time, Defendant Baxter sold the adulterated IV drugs to hospitals and other medical providers through its Medical Products Division. The hospitals and other healthcare providers placed orders for those drugs electronically through Baxter's eServices Center online portal, or using Electronic Data Interchange ("EDI") or Global Healthcare Exchange ("GHX").

201) Pursuant to these sales, Defendant Baxter made claims for payment from the purchasing healthcare provider.

202) In so doing, Defendant Baxter caused the purchasing healthcare providers to make claims for payment on the United States for the adulterated IV drugs.

203) Virtually all of these hospitals provided care to Medicare, TRICARE, and Medicaid recipients.

204) Medicare is the nation's healthcare program for people over 65 and some disabled people. It is administered by the United States through CMS.

205) Through Medicare Part A, CMS reimburses healthcare providers rendering care to its beneficiaries who have been admitted to the hospital for treatment. This is called inpatient care.

206) Through Medicare Part B, CMS reimburses healthcare providers for hospital-based outpatient care, which would include treatment in a hospital's emergency department, urgent care center, and most same-day surgery centers.

207) Medicare providers receive those reimbursements from the United States though a payment system that CMS administers, and to advance and support the Government's Medicare program.

208) The DOD administers the TRICARE healthcare program for active duty military personnel, military retirees, and their families. Like Medicare, TRICARE is an insurance program that covers a broad range of services in both inpatient and outpatient settings. TRICARE reimburses healthcare providers for both hospital inpatient and outpatient treatment.

209) TRICARE providers receive those reimbursements from the United States though a payment system that DOD administers, and to advance and support the Government's TRICARE program. When the adulterated IV drugs produced on Line 11 were administered to inpatient Medicare and TRICARE recipients, the provider was reimbursed for those IV drugs by the United States by submitting a claim to CMS based upon a "Diagnosis-Related Group" code ("DRG").

210) When the adulterated IV drugs produced on Line 11 were administered to outpatient Medicare and TRICARE recipients, the provider was reimbursed for those drugs by the United States by submitting a claim to CMS based upon an "Ambulatory Payment Classification" code ("APC").

211) DRG and APC reimbursement rates are determined based upon diagnosis, age, sex, discharge status, and comorbidities, and then predicting the likely amount of hospital

resources which will be consumed by a patient encounter or hospital case. The DRG or APC reimbursement pays the provider for delivery of the component procedures, including overhead, supplies, and equipment.

212) The administration of the type of IV drugs produced on Line 11 was known and predictable for certain procedures, and the providers' cost of purchasing them was a component of the DRG and APC reimbursements.

213) During the relevant time, when the adulterated Baxter IV drugs were administered to Medicare and TRICARE beneficiaries, the providers submitted claims for reimbursement to, and were reimbursed for those IVs by, the United States as part of the applicable DRG or APC payment for that patient encounter, which payments were made to support the Government's Medicare and Tricare programs.

214) Throughout the relevant t48ime and in violation of 31 U.S.C. § 3729(a)(1)(A), Defendant Baxter knowingly presented false claims for payment to providers giving care under the Medicare and TRICARE programs, in as much as the invoices submitted pursuant to the sales Agreement constituted false certifications of a material condition to payment, to wit, that the drugs conformed to Baxter's specifications and were not adulterated.

215) Throughout the relevant time and in violation of 31 U.S.C. § 3729(a)(1)(B), Defendant Baxter knowingly made and used false statements to providers giving care under the Medicare and TRICARE programs, to wit, the false warranty contained in the sales contract and product inserts stating that the adulterated IV drugs conformed to Defendant Baxter's specifications, and those false statements had the natural tendency to influence payment of the false and fraudulent claims.

216) Throughout the relevant time and in violation of 31 U.S.C. § 3729(a)(1)(B), Defendant Baxter knowingly made and used false process control records, including but not limited to the "2012 HEPA certification report," which concealed the fact that the IV drugs produced on Line 11 were adulterated, and those false records had the natural tendency to influence payment of the false and fraudulent claims by providers giving care under the Medicare and TRICARE programs.

217) Throughout the relevant time and in violation of 31 U.S.C. § 3729(a)(1)(B), Defendant Baxter made and used false statements, to wit, entering into the sale of the adulterated IV drugs to the providers giving care under the Medicare and TRICARE programs when Defendant Baxter had a legal duty to disclose the fact that they were adulterated and did not do so, and that omission had the natural tendency to influence payment of the false and fraudulent claims.

D. False Claims on Recipients of Federal and State Government Funds Through Medicaid and Other Programs

218) Medicaid is the nation's medical assistance program for the needy, the medically-needy aged, blind and disabled, and families with dependent children. It is administered, and reimbursement is made to providers by the states.

219) Through the Medicaid programs, the state governments reimburse hospitals and providers rendering inpatient care to their Medicaid beneficiaries, which includes providing IV drugs.

220) Through the Medicaid program, the state governments also reimburse outpatient care providers for infusible drugs that are furnished and administered as part of a physician

service. With regard to IV drugs, this would typically include (but not be limited to) IV's provided during emergency room care and outpatient surgery.

221) The cost of the adulterated IV drugs purchased from Defendant Baxter was reimbursed by the states to the providers through DRG and APC payments as set forth above.

222) The United States pays for a portion of the states' Medicaid expenditures indirectly by reimbursing an average of approximately 55% of the states' costs. Like Medicare, Medicaid covers both inpatient and outpatient care, and thus pays for IV drugs in the same manner.

223) After reimbursement from the Federal Government is deducted from the total cost of care, the state governments pay an average of 45% of the IV drugs administered through their Medicaid programs.

224) There is no Federal requirement that states provide health coverage to adults without dependent children. These adults qualify for Medicaid coverage only if they have a disability or are 56 or older.

225) Many state governments, however, reimburse hospitals and providers who render care to non-disabled adults who have limited incomes but do not otherwise qualify for the Medicaid program. Through these non-Medicaid medical assistance programs, many of the state governments reimburse hospitals and other providers for the costs associated with medical care, including IV drugs, of such non-Medicaid beneficiaries.

226) Throughout the relevant time and in violation of 31 U.S.C. § 3729(a)(1)(A), Defendant Baxter knowingly presented false claims for payment to providers giving care under

Medicaid and other state healthcare programs administering the Federal and state Medicaid funds, in as much as the invoices submitted pursuant to the sales Agreement constituted false certifications of a material condition to payment, to wit, that the drugs conformed to Baxter's specifications and were not adulterated.

227) Throughout the relevant time and in violation of 31 U.S.C. § 3729(a)(1)(B) and various state FCAs, Defendant Baxter knowingly made and used false statements to providers giving care under Medicaid and other state healthcare programs administering the Federal and state Medicaid funds, to wit, the false warranty contained in the sales contract stating that the adulterated IV drugs conformed to Defendant Baxter's specifications, and that false statement had the natural tendency to influence payment of the false and fraudulent claims.

228) Throughout the relevant time and in violation of 31 U.S.C. § 3729(a)(1)(B) and various state FCAs, Defendant Baxter knowingly made and used false process control records, including but not limited to the "2012 HEPA certification report," which concealed the fact that the IV drugs produced on Line 11 were adulterated, and those false records had the natural tendency to influence payment of the false and fraudulent claims by providers giving care under the Medicaid and other state healthcare programs administering the Federal and state Medicaid funds.

229) Throughout the relevant time and in violation of 31 U.S.C. § 3729(a)(1)(B) and various state FCAs, Defendant Baxter made and used false statements, to wit, entering into the sale of the adulterated IV drugs to the providers giving care under the Medicaid and other state healthcare programs administering the Federal and state Medicaid funds, when Defendant

Baxter had a legal duty to disclose the fact that they were adulterated and did not do so, and that omission had the natural tendency to influence payment of the false and fraudulent claims.

X. DAMAGES

230) The United States and state governments were damaged in the amount of money they paid on false claims for the adulterated IV drugs produced on Line 11 during the relevant time.

231) The United States paid on false claims for the adulterated drugs (a) made directly by Defendant Baxter for purchases by the VHA, DOD and other Federal healthcare providers, (b) through reimbursement to medical providers as recipients of the Government's Medicare and TRICARE programs where the funds were reimbursed by the Government through DRGs and APCs, and (c) through reimbursement to medical providers as recipients of the states and Federal Government under Medicaid and other state healthcare programs.

232) The state governments paid on false claims for the adulterated drugs through their reimbursement to medical providers through the Medicaid program.

CAUSES OF ACTION

CLAIM ONE – FALSE CLAIMS
U.S.C. § 3729(a)(1)(A)

233) Paragraphs 1-232 are re-alleged and incorporated by reference as though fully set forth herein.

234) This is a claim for penalties and treble damages under the Federal False Claims Act.

235) By virtue of the acts described above, Defendant Baxter knowingly presented, or caused to be presented, false or fraudulent claims for payment on the Government in violation of the False Claims Act, 31 U.S.C. § 3729(a)(1)(A) and § 3729(b)(2)(A)(i).

236) By virtue of the acts described above, Defendant Baxter knowingly presented, or caused to be presented, false or fraudulent claims for payment on recipients of Government money, where the money was used to advance the Government's Medicare, TRICARE and Medicaid programs, and where the Government either provided or reimbursed the money to the recipients, these acts being in violation of 31 U.S.C. § 3729(a)(1)(A) and § 3729(b)(2)(A)(ii).

237) United States funds were lost through payments and reimbursements made on and for the claims.

238) Because of Defendant Baxter's acts, the United States sustained damages in an amount to be determined at trial.

CLAIM TWO – FALSE STATEMENTS AND RECORDS
U.S.C. § 3729(a)(1)(B)

239) Paragraphs 1-232 are re-alleged and incorporated by reference as though fully set forth herein.

240) This is a claim for penalties and treble damages under the Federal False Claims Act.

241) By virtue of the acts described above, Defendant Baxter knowingly made, used, or caused to be made or used, false records or statements which were material to false or

fraudulent claims made on the Government in violation of the False Claims Act, 31 U.S.C. § 3729(a)(1)(B) and § 3729(b)(2)(A)(i).

242) By virtue of the acts described above, Defendant Baxter knowingly made, used, or caused to be made or used, false records or statements which were material to false or fraudulent claims made on recipients of Government money where the money was used to advance the Government's Medicare, TRICARE and Medicaid programs, and where the Government either provided or reimbursed the money to the recipients, these acts being in violation of 31 U.S.C. § 3729(a)(1)(B) and § 3729(b)(2)(A)(ii).

243) United States funds were lost through payments and reimbursements made on and for the claims.

244) Because of Defendant Baxter's acts, the United States sustained damages in an amount to be determined at trial.

CLAIM THREE – FALSE CLAIMS
CALIFORNIA FALSE CLAIMS ACT (Cal. Gov't Code § 12650 et seq.)

245) Paragraphs 1- 232 are re-alleged and incorporated by reference as if fully set forth herein.

246) This is a claim for penalties and treble damages under the California False Claims Act.

247) By virtue of the acts described above, Defendant Baxter knowingly presented or caused to be presented false or fraudulent claims paid by Medicaid and other California state funded programs, in violation of Cal. Gov't Code § 12651(a)(1).

248) California state funds were lost through payments made on the claims.

249) Because of Defendant Baxter's acts, the state of California has sustained damages in an amount to be determined at trial.

250) The state of California is also entitled to the maximum penalty of $11,000 for each and every false claim paid or approved arising from Defendant Baxter's fraudulent conduct.

CLAIM FOUR – FALSE STATEMENTS AND RECORDS
CALIFORNIA FALSE CLAIMS ACT (Cal. Gov't Code § 12650 et seq.)

251) Paragraphs 1- 232 are re-alleged and incorporated by reference as if fully set forth herein.

252) This is a claim for penalties and treble damages under the California False Claims Act.

253) By virtue of the acts described above, Defendant Baxter knowingly made, used, or caused to be made or used, false records or statements to get false or fraudulent claims paid by Medicaid and other California state funded programs, in violation of Cal. Gov't Code § 12651(a)(2).

254) California state funds were lost through payments made on the claims.

255) Because of Defendant Baxter's acts, the state of California has sustained damages in an amount to be determined at trial.

256) The state of California is also entitled to the maximum penalty of $11,000 for each and every false claim paid or approved arising from Defendant Baxter's fraudulent conduct.

CLAIM FIVE – FALSE CLAIMS
COLORADO MEDICAID FALSE CLAIMS ACT (Colo. Rev. Stat. § 25.5-4-303.5 et seq.)

257) Paragraphs 1-232 are re-alleged and incorporated by reference as if fully set forth herein.

258) This is a claim for penalties and treble damages under the Colorado Medicaid False Claims Act.

259) By virtue of the acts described above, Defendant Baxter knowingly presented or caused to be presented to an officer of the state of Colorado, false claims for payment, in violation of Colo. Rev. Stat. § 25.5-4-305(1)(a).

260) Colorado state funds were lost through payments made on the claims.

261) Because of Defendant Baxter's acts, the state of Colorado has sustained damages in an amount to be determined at trial.

262) The state of Colorado is also entitled to the maximum penalty of $10,000 for each and every false claim paid or approved arising from Defendant Baxter's fraudulent conduct.

CLAIM SIX – FALSE STATEMENTS AND RECORDS
COLORADO MEDICAID FALSE CLAIMS ACT (Colo. Rev. Stat. § 25.5-4-303.5 et seq.)

263) Paragraphs 1-232 are re-alleged and incorporated by reference as if fully set forth herein.

264) This is a claim for penalties and treble damages under the Colorado Medicaid False Claims Act.

265) By virtue of the acts described above, Defendant Baxter knowingly made, used, or caused to be made or used, false records or statements to get false or fraudulent claims paid by Medicaid and other Colorado state funded programs, in violation of Colo. Rev. Stat. § 25.5-4-305(1)(b).

266) Colorado state funds were lost through payments made on the claims.

267) Because of Defendant Baxter's acts, the state of Colorado has sustained damages in an amount to be determined at trial.

268) The state of Colorado is also entitled to the maximum penalty of $10,000 for each and every false claim paid or approved arising from Defendant Baxter's fraudulent conduct.

CLAIM SEVEN – FALSE CLAIMS
CONNECTICUT FALSE CLAIMS ACT (Conn. Gen. Stat. § 17b-301a et seq.)

269) Paragraphs 1-232 are re-alleged and incorporated by reference as if fully set forth herein.

270) This is a claim for penalties and treble damages under the Connecticut False Claims Act.

271) By virtue of the acts described above, Defendant Baxter knowingly presented or caused to be presented, to an officer of the state of Connecticut, false or fraudulent claims for payment under Medicaid, a medical assistance program administered by its Department of Social Services, and other Connecticut state funded programs, in violation of Conn. Gen. Stat. § 17b-301b(a)(1).

272) Connecticut state funds were lost through payments made on the claims.

273) Because of Defendant Baxter's acts, the state of Connecticut has sustained damages in an amount to be determined at trial.

274) The state of Connecticut is also entitled to the maximum penalty of $10,000 for each and every false claim paid or approved arising from Defendant Baxter's fraudulent conduct.

CLAIM EIGHT – FALSE STATEMENTS AND RECORDS
CONNECTICUT FALSE CLAIMS ACT (Conn. Gen. Stat. § 17b-301a et seq.)

275) Paragraphs 1-232 are re-alleged and incorporated by reference as if fully set forth herein.

276) This is a claim for penalties and treble damages under the Connecticut False Claims Act.

277) By virtue of the acts described above, Defendant Baxter knowingly made, used, or caused to be made or used, false records or statements to get false or fraudulent claims paid by the state of Connecticut under Medicaid, a medical assistance program administered by its

Department of Social Services, and other Connecticut state funded programs, in violation of Conn. Gen. Stat. § 17b-301b(a)(2).

278) Connecticut state funds were lost through payments made on the claims.

279) Because of Defendant Baxter's acts, the state of Connecticut has sustained damages in an amount to be determined at trial.

280) The state of Connecticut is also entitled to the maximum penalty of $10,000 for each and every false claim paid or approved arising from Defendant Baxter's fraudulent conduct.

CLAIM NINE – FALSE CLAIMS
(GEORGIA) STATE FALSE MEDICAID CLAIMS ACT (Ga. Code §§ 49-4-168 et seq.)

281) Paragraphs 1-232 are re-alleged and incorporated by reference as if fully set forth herein.

282) This is a claim for penalties and treble damages under the Georgia State False Medicaid Claims Act.

283) By virtue of the acts described above, Defendant Baxter knowingly presented or caused to be presented, false or fraudulent claims to the Georgia Medicaid Program, in violation of Ga. Code §§ 49-4-168.1(a)(1).

284) Georgia state funds were lost through payments made on the claims.

285) Because of Defendant Baxter's acts, the state of Georgia has sustained damages in an amount to be determined at trial.

286) The state of Georgia is also entitled to the maximum penalty of $11,000 for each and every false claim paid or approved arising from Defendant Baxter's fraudulent conduct.

CLAIM TEN – FALSE STATEMENTS AND RECORDS
(GEORGIA) STATE FALSE MEDICAID CLAIMS ACT (Ga. Code §§ 49-4-168 et seq.)

287) Paragraphs 1-232 are re-alleged and incorporated by reference as if fully set forth herein.

288) This is a claim for penalties and treble damages under the Georgia State False Medicaid Claims Act.

289) By virtue of the acts described above, Defendant Baxter knowingly made, used, or caused to be made or used, false records or statements to get false or fraudulent claims paid by the Georgia Medicaid Program, in violation of Ga. Code §§ 49-4-168.1(a)(2).

290) Georgia state funds were lost through payments made on the claims.

291) Because of Defendant Baxter's acts, the state of Georgia has sustained damages in an amount to be determined at trial.

292) The state of Georgia is also entitled to the maximum penalty of $11,000 for each and every false claim paid or approved arising from Defendant Baxter's fraudulent conduct.

CLAIM ELEVEN – FALSE CLAIMS
HAWAII FALSE CLAIMS ACT (Haw. Rev Stat. §§ 661-21 et seq.)

293) Paragraphs 1-232 are re-alleged and incorporated by reference as if fully set forth herein.

294) This is a claim for penalties and treble damages under the Hawaii False Claims Act.

295) By virtue of the acts described above, Defendant Baxter knowingly presented or caused to be presented, false or fraudulent claims for payment to the state of Hawaii under Medicaid, and other Hawaii state funded programs, in violation of Haw. Rev. Stat. § 661-21(a)(1).

296) Hawaii state funds were lost through payments made on the claims.

297) Because of Defendant Baxter's acts, the state of Hawaii has sustained damages in an amount to be determined at trial.

298) The state of Hawaii is also entitled to the maximum penalty of $10,000 for each and every false claim paid or approved arising from Defendant Baxter's fraudulent conduct.

CLAIM TWELVE – FALSE STATEMENTS AND RECORDS
HAWAII FALSE CLAIMS ACT (Haw. Rev Stat. §§ 661-21 et seq.)

299) Paragraphs 1-232 are re-alleged and incorporated by reference as if fully set forth herein.

300) This is a claim for penalties and treble damages under the Hawaii False Claims Act.

301) By virtue of the acts described above, Defendant Baxter knowingly made, used, or caused to be made or used, false records or statements to get false or fraudulent claims paid by the state of Hawaii under Medicaid, and other Hawaii state funded programs, in violation of Haw. Rev. Stat. § 661-21(a)(2).

302) Hawaii state funds were lost through payments made on the claims.

303) Because of Defendant Baxter's acts, the state of Hawaii has sustained damages in an amount to be determined at trial.

304) The state of Hawaii is also entitled to the maximum penalty of $10,000 for each and every false claim paid or approved arising from Defendant Baxter's fraudulent conduct.

CLAIM THIRTEEN – FALSE CLAIMS
ILLINOIS FALSE CLAIMS WHISTLEBLOWER REWARD AND PROTECTION ACT
(740 Ill. Comp. Stat. §§ 175/1 et seq.)

305) Paragraphs 1-232 are re-alleged and incorporated by reference as if fully set forth herein.

306) This is a claim for penalties and treble damages under the Illinois False Claims Whistleblower Reward and Protection Act.

307) By virtue of the acts described above, Defendant Baxter knowingly presented or caused to be presented, false or fraudulent claims for payment to the state of Illinois under Medicaid, and other Illinois state funded programs, in violation of 740 Ill. Comp. Stat. §§ 175/3(a)(1)(B)(1).

308) Illinois state funds were lost through payments made on the claims.

309) Because of Defendant Baxter's acts, the state of Illinois has sustained damages in an amount to be determined at trial.

310) The state of Illinois is also entitled to the maximum penalty of $11,000 for each and every false claim paid or approved arising from Defendant Baxter's fraudulent conduct.

CLAIM FOURTEEN – FALSE STATEMENTS AND RECORDS
ILLINOIS FALSE CLAIMS WHISTLEBLOWER REWARD AND PROTECTION ACT
(740 Ill. Comp. Stat. §§ 175/1 et seq.)

311) Paragraphs 1-232 are re-alleged and incorporated by reference as if fully set forth herein.

312) This is a claim for penalties and treble damages under the Illinois False Claims Whistleblower Reward and Protection Act.

313) By virtue of the acts described above, Defendant Baxter knowingly made, used, or caused to be made or used, false records or statements to get false or fraudulent claims paid by the state of Illinois under Medicaid, and other Illinois state funded programs, in violation of 740 Ill. Comp. Stat. §§ 175/3(a)(1)(B)(2).

314) Illinois state funds were lost through payments made on the claims.

315) Because of Defendant Baxter's acts, the state of Illinois has sustained damages in an amount to be determined at trial.

316) The state of Illinois is also entitled to the maximum penalty of $11,000 for each and every false claim paid or approved arising from Defendant Baxter's fraudulent conduct.

CLAIM FIFTEEN – FALSE CLAIMS
IOWA FALSE CLAIMS ACT (Iowa Code §§ 685.1 et seq.)

317) Paragraphs 1-232 are re-alleged and incorporated by reference as if fully set forth herein.

318) This is a claim for penalties and treble damages under the Iowa False Claims Act.

319) By virtue of the acts described above, Defendant Baxter knowingly presented or caused to be presented false or fraudulent claims for payment to the state of Iowa under Medicaid, and other Iowa state funded programs, in violation of Iowa Code § 685.2(1)(a).

320) Iowa state funds were lost through payments made on the claims.

321) Because of Defendant Baxter's acts, the state of Iowa has sustained damages in an amount to be determined at trial.

322) The state of Iowa is also entitled to a maximum penalty of $10,000 for each and every false claim paid or approved arising from Defendant Baxter's fraudulent conduct.

CLAIM SIXTEEN – FALSE STATEMENTS AND RECORDS
IOWA FALSE CLAIMS ACT (Iowa Code §§ 685.1 et seq.)

323) Paragraphs 1-232 are re-alleged and incorporated by reference as if fully set forth herein.

324) This is a claim for penalties and treble damages under the Iowa False Claims Act.

325) By virtue of the acts described above, Defendant Baxter knowingly made, used, or caused to be made or used, false records or statements to get false or fraudulent claims paid by the state of Iowa under Medicaid, and other Iowa state funded programs, in violation of Iowa Code § 685.2(1)(b).

326) Iowa state funds were lost through payments made on the claims.

327) Because of Defendant Baxter's acts, the state of Iowa has sustained damages in an amount to be determined at trial.

328) The state of Iowa is also entitled to a maximum penalty of $10,000 for each and every false claim paid or approved arising from Defendant Baxter's fraudulent conduct.

CLAIM SEVENTEEN – FALSE CLAIMS
MARYLAND FALSE HEALTH CLAIMS ACT OF 2010
(Md. Code Ann., Com. Law § 2-601 et seq.)

329) Paragraphs 1-232 are re-alleged and incorporated by reference as if fully set forth herein.

330) This is a claim for penalties and treble damages under the Maryland False Health Claims Act of 2010.

331) By virtue of the acts described above, Defendant Baxter knowingly made or caused to be made, false or fraudulent claims for payment to the state of Maryland under Medicaid, and other Maryland state funded programs, in violation of Md. Code Ann., Com. Law § 2-602(a)(1).

332) Maryland state funds were lost through payments made on the claims.

333) Because of Defendant Baxter's acts, the state of Maryland has sustained damages in an amount to be determined at trial.

334) The state of Maryland is also entitled to a maximum penalty of $10,000 for each and every false claim paid or approved arising from Defendant Baxter's fraudulent conduct.

CLAIM EIGHTEEN – FALSE STATEMENTS AND RECORDS

MARYLAND FALSE HEALTH CLAIMS ACT OF 2010
(Md. Code Ann., Com. Law § 2-601 et seq.)

335) Paragraphs 1-232 are re-alleged and incorporated by reference as if fully set forth herein.

336) This is a claim for penalties and treble damages under the Maryland False Health Claims Act of 2010.

337) By virtue of the acts described above, Defendant Baxter knowingly made, used, or caused to be made or used, false records or statements to get false or fraudulent claims paid by the state of Maryland under Medicaid, and other Maryland state funded programs, in violation of Md. Code Ann., Com. Law § 2-602(a)(2).

338) Maryland state funds were lost through payments made on the claims.

339) Because of Defendant Baxter's acts, the state of Maryland has sustained damages in an amount to be determined at trial.

340) The state of Maryland is also entitled to a maximum penalty of $10,000 for each and every false claim paid or approved arising from Defendant Baxter's fraudulent conduct.

CLAIM NINETEEN – FALSE CLAIMS
MASSACHUSETTS FALSE CLAIMS ACT
(Mass. Gen. Laws Ch. 159, §§ 5A et seq.)

341) Paragraphs 1-232 are re-alleged and incorporated by reference as if fully set forth herein.

342) This is a claim for penalties and treble damages under the Massachusetts False Claims Act.

343) By virtue of the acts described above, Defendant Baxter knowingly presented or caused to be presented, false or fraudulent claims for payment to the state of Massachusetts under Medicaid, and other Massachusetts state funded programs, in violation of Mass. Gen. Laws Ch. 159, § 5B(1).

344) Massachusetts state funds were lost through payments made on the claims.

345) Because of Defendant Baxter's acts, the state of Massachusetts has sustained damages in an amount to be determined at trial.

346) The state of Massachusetts is also entitled to a maximum penalty of $10,000 for each and every false claim paid or approved arising from Defendant Baxter's fraudulent conduct.

CLAIM TWENTY – FALSE STATEMENTS AND RECORDS
MASSACHUSETTS FALSE CLAIMS ACT
(Mass. Gen. Laws Ch. 159, §§ 5A et seq.)

347) Paragraphs 1-232 are re-alleged and incorporated by reference as if fully set forth herein.

348) This is a claim for penalties and treble damages under the Massachusetts False Claims Act.

349) By virtue of the acts described above, Defendant Baxter knowingly made, used, or caused to be made or used, false records or statements to get false or fraudulent claims paid by the state of Massachusetts under Medicaid, and other Massachusetts state funded programs, in violation of Mass. Gen. Laws Ch. 159, § 5B(2).

350) Massachusetts state funds were lost through payments made on the claims.

351) Because of Defendant Baxter's acts, the state of Massachusetts has sustained damages in an amount to be determined at trial.

352) The state of Massachusetts is also entitled to a maximum penalty of $10,000 for each and every false claim paid or approved arising from Defendant Baxter's fraudulent conduct.

CLAIM TWENTY-ONE – FALSE CLAIMS
NEW YORK FALSE CLAIMS ACT
(N.Y. State Finance Law §§ 187 et seq.)

353) Paragraphs 1-232 are re-alleged and incorporated by reference as if fully set forth herein.

354) This is a claim for penalties and treble damages under the New York False Claims Act.

355) By virtue of the acts described above, Defendant Baxter knowingly presented or caused to be presented, false or fraudulent claims for payment to the state of New York under Medicaid, and other New York state funded programs, in violation of N.Y. State Finance Law § 189(1)(a).

356) New York state funds were lost through payments made on the claims.

357) Because of Defendant Baxter's acts, the state of New York has sustained damages in an amount to be determined at trial.

358) The state of New York is also entitled to a maximum penalty of $12,000 for each and every false claim paid or approved arising from Defendant Baxter's fraudulent conduct.

CLAIM TWENTY-TWO – FALSE STATEMENTS AND RECORDS
NEW YORK FALSE CLAIMS ACT
(N.Y. State Finance Law §§ 187 et seq.)

359) Paragraphs 1-232 are re-alleged and incorporated by reference as if fully set forth herein.

360) This is a claim for penalties and treble damages under the New York False Claims Act.

361) By virtue of the acts described above, Defendant Baxter knowingly made, used, or caused to be made or used, false records or statements to get false or fraudulent claims paid by the state of New York under Medicaid, and other New York state funded programs, in violation of N.Y. State Finance Law § 189(1)(b).

362) New York state funds were lost through payments made on the claims.

363) Because of Defendant Baxter's acts, the state of New York has sustained damages in an amount to be determined at trial.

364) The state of New York is also entitled to a maximum penalty of $12,000 for each and every false claim paid or approved arising from Defendant Baxter's fraudulent conduct.

CLAIM TWENTY-THREE – FALSE CLAIMS
NORTH CAROLINA FALSE CLAIMS ACT
(N.C.G.S. §§ 1-605 et seq.)

365) Paragraphs 1-232 are re-alleged and incorporated by reference as if fully set forth herein.

366) This is a claim for penalties and treble damages under the North Carolina False Claims Act.

367) By virtue of the acts described above, Defendant Baxter knowingly presented or caused to be presented, false or fraudulent claims for payment to the state of North Carolina under Medicaid, and other North Carolina state funded programs, in violation of N.C.G.S. § 1-607(a)(1).

368) North Carolina state funds were lost through payments made on the claims.

369) Because of Defendant Baxter's acts, the state of North Carolina has sustained damages in an amount to be determined at trial.

370) The state of North Carolina is also entitled to a maximum penalty of $11,000 for each and every false claim paid or approved arising from Defendant Baxter's fraudulent conduct.

CLAIM TWENTY-FOUR – FALSE STATEMENTS AND RECORDS NORTH CAROLINA FALSE CLAIMS ACT (N.C.G.S. §§ 1-605 et seq.)

371) Paragraphs 1-232 are re-alleged and incorporated by reference as if fully set forth herein.

372) This is a claim for penalties and treble damages under the North Carolina False Claims Act.

373) By virtue of the acts described above, Defendant Baxter knowingly made, used, or caused to be made or used, false records or statements to get false or fraudulent claims paid by the state of North Carolina under Medicaid, and other North Carolina state funded programs, in violation of N.C.G.S. § 1-607(a)(2).

374) North Carolina state funds were lost through payments made on the claims.

375) Because of Defendant Baxter's acts, the state of North Carolina has sustained damages in an amount to be determined at trial.

376) The state of North Carolina is also entitled to a maximum penalty of $11,000 for each and every false claim paid or approved arising from Defendant Baxter's fraudulent conduct.

CLAIM TWENTY-FIVE – FALSE CLAIMS
VIRGINIA FRAUD AGAINST THE TAXPAYERS ACT
(Va. Code Ann. §§ 8.01-216.1 et seq.)

377) Paragraphs 1-232 are re-alleged and incorporated by reference as if fully set forth herein.

378) This is a claim for penalties and treble damages under the Virginia Fraud Against the Taxpayers Act.

379) By virtue of the acts described above, Defendant Baxter knowingly presented or caused to be presented, false or fraudulent claims for payment to the state of Virginia under Medicaid, and other Virginia state funded programs, in violation of Va. Code Ann. § 8.01-216.3(A)(1).

380) Virginia state funds were lost through payments made on the claims.

381) Because of Defendant Baxter's acts, the state of Virginia has sustained damages in an amount to be determined at trial.

382) The state of Virginia is also entitled to a maximum penalty of $11,000 for each and every false claim paid or approved arising from Defendant Baxter's fraudulent conduct.

CLAIM TWENTY-SIX – FALSE STATEMENTS AND RECORDS
VIRGINIA FRAUD AGAINST THE TAXPAYERS ACT
(Va. Code Ann. §§ 8.01-216.1 et seq.)

383) Paragraphs 1-232 are re-alleged and incorporated by reference as if fully set forth herein.

384) This is a claim for penalties and treble damages under the Virginia Fraud Against the Taxpayers Act.

385) By virtue of the acts described above, Defendant Baxter knowingly made, used, or caused to be made or used, false records or statements to get false or fraudulent claims paid by the state of Virginia under Medicaid, and other Virginia state funded programs, in violation of Va. Code Ann. § 8.01-216.3(A)(2).

386) Virginia state funds were lost through payments made on the claims.

387) Because of Defendant Baxter's acts, the state of Virginia has sustained damages in an amount to be determined at trial.

388) The state of Virginia is also entitled to a maximum penalty of $11,000 for each and every false claim paid or approved arising from Defendant Baxter's fraudulent conduct.

CLAIM TWENTY-SEVEN – FALSE CLAIMS
WASHINGTON STATE MEDICAID FRAUD FALSE CLAIMS ACT
(Wash. Rev. Code §§ 74.66.05 et seq.)

389) Paragraphs 1-232 are re-alleged and incorporated by reference as if fully set forth herein.

390) This is a claim for penalties and treble damages under the Washington State Medicaid Fraud False Claims Act.

391) By virtue of the acts described above, Defendant Baxter knowingly presented or caused to be presented, false or fraudulent claims for payment to the state of Washington under Medicaid, and other Washington state funded programs, in violation of Wash. Rev. Code §§ 74.66.020(1)(a).

392) Washington state funds were lost through payments made on the claims.

393) Because of Defendant Baxter's acts, the state of Washington has sustained damages in an amount to be determined at trial.

394) The state of Washington is also entitled to a maximum penalty of $11,000 for each and every false claim paid or approved arising from Defendant Baxter's fraudulent conduct.

CLAIM TWENTY-EIGHT – FALSE STATEMENTS AND RECORDS
WASHINGTON STATE MEDICAID FRAUD FALSE CLAIMS ACT
(Wash. Rev. Code §§ 74.66.05 et seq.)

395) Paragraphs 1-232 are re-alleged and incorporated by reference as if fully set forth herein.

396) This is a claim for penalties and treble damages under the Washington State Medicaid Fraud False Claims Act.

397) By virtue of the acts described above, Defendant Baxter knowingly made, used, or caused to be made or used, false records or statements to get false or fraudulent claims paid by the state of Washington under Medicaid, and other Washington state funded programs, in violation of Wash. Rev. Code §§ 74.66.020(1)(b).

398) Washington state funds were lost through payments made on the claims.

399) Because of Defendant Baxter's acts, the state of Washington has sustained damages in an amount to be determined at trial.

400) The state of Washington is also entitled to a maximum penalty of $11,000 for each and every false claim paid or approved arising from Defendant Baxter's fraudulent conduct.

PRAYER FOR RELIEF

WHEREFORE, on behalf of the United States for Claim One and Two, and the state governments for Claims Three through Twenty-eight, Relator Wall seeks the following relief from the Defendants Baxter International, Inc. and Baxter Healthcare Corporation, jointly and severally:

A. Three times the amount of damages that the United States and state governments have sustained because of the acts of the Defendants;

B. A civil penalty for each violation as allowed by the applicable FCA statute;

C. An award to Relator Wall of the maximum amount allowed pursuant to 31 U.S.C. § 3730(d) including the costs and expenses of this action;

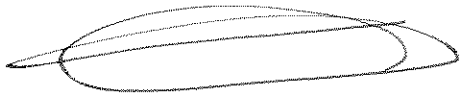
D. An award of Relator Wall's reasonable attorney fees; and

E. Such further relief as the Court deems just.

DEMAND FOR JURY TRIAL

Plaintiff demands that his claims for relief against the Defendants be tried by a jury to the full extent permitted by law.

Respectfully submitted, this the 28 day of January, 2015.



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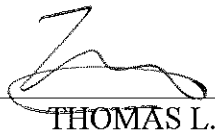

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CERTIFICATE OF SERVICE

I hereby certify that I am serving a copy of the attached "Second Amended False Claims Act Complaint and Demand for Jury Trial" on the United States and the following States by either Federal Express overnight delivery or personal service as indicated addressed to:

1. The Honorable Eric H. Holder, Jr.
United States of America
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This the 28th day of January, 2015.

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